Secretary of the Air Force
Office of Legislative Liaison

C O N G R E S S I O N A L
HEARING RESUME

106th Congress

Date: 13 July 00

SUBJECT: **Anthrax Vaccine Immunization Program (AVIP)**

COMMITTEE: **House Armed Services Committee, Subcommittee on Military Personnel**

CHAIRMAN: **The Honorable Steven Buyer (R-IN)**

Committee Members (bold type indicates member was present):

Republicans	**Democrats**
Steven Buyer (IN)	**Neil Abercrombie (D-HI)**
Roscoe Bartlett (MD)	Martin Meehan (MA)
J.C Watts (OK)	Patrick Kennedy (RI)
William Thornberry (TX)	Loretta Sanchez (CA)
Lindsey Graham (SC)	Ellen Tauscher CA
Jim Ryun (KS)	**Mike Thompson (CA)**
Mary Bono CA)	**John Larson (CT)**
Joe Pitts (PA)	
Robin Hayes (NC)	
Steven Kuykendall (CA)	

Non-Subcommittee Members Present:
CM Walter Jones (R-NC), full HASC committee member
CM Christorpher Shays (R-CT), Government Reform Committee

WITNESSES: See Attached

Information contained in this resume was obtained during an open hearing. It will not be released outside of the Department of Defense (DoD) agencies until published hearing transcripts have been released by the Committee, and only to the extent it is in accord with published hearing procedures.

Prepared by: Lt Col Meade Pimsler **Date: 14 July 00** **Phone number: 693-9120**

Panel Members

Panel I

Mr. Rudy DeLeon, DEPSECDEF
Gen Franks, CINC, CENTCOM
RADM Jerred Clinton, PHS, Acting ASD(HA)
Maj Gen Randall West, Spec. Adv. To DEPSECDEF
Ms. Anna Johnson-Winegar, DASD(CBD)
COL Randy Randolph, Director, AVIP

Panel II

Dr. Katherine Zoon, Director, Center for Biologics Evaluation and Research, FDA
Ms. April Stephenson, Chief, Policy Programs Division, Defense Contract Audit Agency

Panel III

Mr. Fad El-Hibri, President and Chief Executive Officer, Bioport Corporation

EXECUTIVE SUMMARY

The hearing focused on the reasons for and DoD response to the current anthrax vaccine shortage. All members concurred that the threat was real and that immunizing with safe and effective vaccine was the appropriate force protection strategy. DoD was heavily criticized for a flawed acquisition strategy with based the success of the entire AVIP on Bioport. Questions to the panels focused on vaccine supply; FDA approval of vaccine, Bioport and DoD slow-down plan; costs associated with supporting Bioport to date; and contingeny planning for the future of the AVIP that included not only Bioport but other sources of vaccine as well, including the possibility of a GOCO.

In response to questions from the members, DoD witnesses addressed the 1) overall acquisition strategy which made Bioport the sole source for the vaccine, 2) the money that had already been spent to bring that production facility online, 3) the short-medium-long-term contingency plans for dealing with the vaccine supply issue, including manufacturers other than Bioport, 4) development of new vaccines, and 5) BW detection and decontamination capabilities in theater. DoD was also asked to defend the temporary slow-down strategy announced by SECDEF on Monday, and to comment on whether the decision to defer vaccinating troop who had already started the series but were no longer deployed to high-threat areas constituted a deliberate break with FDA approved protocols. DoD explained the current strategy, said that we were actively engaged in seeking a second commercial manufacturer for the vaccine, and would reconsider the feasibility of a Government-Owned/Contractor-Operated (GOCO) facility for manufacture of defense vaccines. In addition, the current strategy re: deferment was IAW CDC guidelines for dealing with vaccine shortages. In response to questioning by Mr. Buyer, Gen Franks discussed the strengths and limitations of current BW agent detection capability in theater, and why immunization was so important.

FDA testified about the deficiencies noted in the production facility at Bioport. Bioport was making progress toward meeting good manufacturing practice (GMP) standards and could be reasonably be expected to be approved by FDA in 6-12 months. Also, that while FDA did not approve of departure from approved vaccination schedules, the FDA was working with DoD and did not object to the current deferment plan. DCAA stated that Bioport was in compliance with the terms of the contract. Also, since Bioport had only

one product (anthrax vaccine) and one customer (DoD), it was fair to say that Bioport could not survive without DoD support.

Mr. El-Hibri testified about the financial situation of the company, the contract actions with the DoD, and the difficulties the company had faced in achieving FDA approval to produce anthrax vaccine. Also discussed Bioport action to get efficacy tests working again (are currently invalid).

The Subcommittee was called to order at 1007, adjourned at 1530.

TRANSCRIPTS AND WITNESS STATEMENTS ATTACHED: RESUME WILL ADDRESS ONLY HIGHLIGHTS

Panel I Highlights:

Opening statements by the members of the subcommittee and visitors acknowledged the severity of the threat and the necessity of vaccination. However, questioned DoD acquisition strategy in light of the severe vaccine shortage and continued failure of Bioport to achieve FDA approval. Stressed the importance of having firm contingency plans not only for continued delay in approval, but for the possibility that Bioport will not be approved at all. In addition, Mr. Jones stated his believe that the American taxpayer was ill served by continued support of a company that could not produce vaccine. Mr. Shays added that we should be expending out time an effort to develop a safe, 21st century vaccine, and not propping up an ill conceived plan based on an invalid 1950s vaccine and production process.

Mr. DeLeon and Gen Franks were the only two witnesses to make statements. The others were on hand to help answer questions.

Mr. DeLeon reviewed history of the AVIP, the vaccine stockpile, quality control testing procedures used before release from the stockpile, and acquisition issues, including current attempt to find a second commercial manufacturer and Defense Review Board plans to reevaluate feasibility of a GOCO for defense vaccine development. He also described the temporary slow-down plan announced by the SECDEF, and asserted that the protection and safety of our troops were the DoD's primary guiding principles.

Gen Franks discussed the reality and growing nature of the BW threat, and discussed capability of Iraq and Iran to produce agent and delivery systems. He reviewed plans to counter that threat in theater, including early detection, vaccine, masks, and other active measures. Stated that temporary slow-down plan was not as good as universal vaccination, but would stretch the availability of the limited amount of certified vaccine, and would permit protection of those most immediately at risk.

During Q&A the following topics were discussed:
- Deterrence and the nature to response the US would make to a BW attack
- Adequacy/inadequacy of current early warning systems for BW attack
- Impact of 30-day rule on AD and ARC members (would affect ARC more).
- Current AVIP program status (#s vaccinated, how many shots, etc.)
- Medical appropriateness of deferral for those not in theater
- Punitive actions against those who continue to refuse vaccination
- DoD systems for tracking vaccination status of all troops individually, VAERS reporting

- Search for alternative sources of vaccine, role of Dyncorp (DoD has contract with Dyncorp to package and distribute vaccine made by Bioport).
- Cost of vaccine, originally $2.36/shot, now over $10.00 per shot (going rate for most vaccines in the US today)
- How US vaccine works and whether it will protect against all known and unknown strains of anthrax
- Details of contractual and financial relationship with Bioport
- Future solvency of Bioport; alternatives, including GOCO for production of new vaccines
- Lessons learned from investment in Bioport
- Safety and efficacy of the vaccine, CDC and FDA evaluation of VAERS reports
- Importance of education of the force on the nature of the threat, the protection afforded by the vaccine, and current data from FDA and CDC on vaccine safety
- Early warning and decontamination (can do for chem, very difficult or not yet possible for bio, esp. Anthrax spores).

In addition, Mr. Bartlett pointed out that unless you were on the cutting edge, you didn't know what was on the cutting edge (in reference to Russian BW research described by Mr. Ken Alibek in his book). Stated we were not on the cutting edge in this arena even since President Nixon had killed our BW program. Stated that he did not want to make BW weapons, but there had to be a happy medium and offered to discuss legislation that would make this possible.

Mr. Shays stated that DoD should not have embarked on this program unless we knew we could actually protect the entire force, and when it became evident we could not (shortage, Bioport problems), we should have suspended the program. Was not moved by argument that the three-phase approach was a way to manage a limited supply until a secure supply source could be established. Stated we should be working towards a 21st century vaccine instead.

CM Buyer closed the panel by saying that the point of the hearing was to ensure that DoD manages the risk posed by weaponized anthrax in the right way, that DoD has done a poor job and waited too long to develop and implement contingency plans.

Panel 2 Highlights:

Dr. Zoon described the entire FDA approval process for vaccines and manufacturing facilities, and placed Bioport approval along that process timeline. She discussed the VAERS reporting system, the history of Michigan Biological Institute, most recent Bioport inspection by the FDA, and progress towards correcting deficiencies (may take another 6-12 months). Reiterated FDA position that vaccine was safe and effective when administered under the approved protocol

Ms. Stevenson described the DCAA mission, her agency's audit of the Bioport contract, and granting Bioport extraordinary contractual relief. Stated the proposal was IAW acquisition rules, and money from contracts had been spend IAW the contract requirements. Stated there was still significant doubt about the solvency of Bioport, and reviewed allegations of irregularities, poor assumptions about approval timelines and cost to get approval.

In the Q and A the following topics were discussed:
- Original timeline was optimistic, but not a totally unreasonable initial estimate

- When will Bioport get well (possibly with 12 months)
- Future solvency of Bioport, with and without DoD support (none without DoD support, as we are their only customer for their only product).
- FDA approval of the deferral plan (deferral do to lack of supply is a known and accepted public health practice)
- Exactly what Bioport bought when they took over Michigan Biologicals (plant, stocks, employees, and all regulatory deficiencies outstanding with the FDA).
- How long it would take a second manufacturer sharing Bioport's license to be approved, if one was found (2-4 years).

Mr. Buyer closed the second panel by stating this is a good story, that the strict standards imposed by the FDA was essential to credibility of the entire AVIP program, that FDA was the much appreciated watchdog of the public trust.

Panel III highlights:

Mr. El-Hibiri stated that the mission of Bioport was to provide DoD with anthrax vaccine. Bioport has one customer and one product right now. Understood but underestimated the challenges when they took over Michigan Biological Institute. Described FDA certification efforts, delays in the renovation project, and challenges related to change in organization culture. Also described new agreements whereby Bioport would not be paid for production until approved for production, and would make no profit while in renovation. Described in some detail the problem they are having with efficacy testing. Specifically, the assay that has been used and accepted by FDA for certification of vaccine from the stockpile is not working now (producing invalid results). Problem is not vaccine potency, they think, but the validity of the test itself. They are looking at all the variables to fix the problem.

During the Q&A the following items were discussed:
- Problems experienced and amount of private (non-DoD) capital invested (millions of dollars, and payroll costs of about $900K/month for 217 employees).
- How Bioport expected to make money at only $2-3 per shot (acquisition regulations prohibited a cost plus arrangement so a faxed price has to be determined, too low; expected to profit from sales of vaccine and other products to private sector and foreign governments).
- Future of the company if not approved in the next 6-7 months
- Cooperation of Bioport with DoD to get a second manufacturer online ASAP.